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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,289	08/10/2000	Volker Landschutze	514413-3834	7068

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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/18/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/636,289

Applicant(s)

Landshutze

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/26/02
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-15 and 19-32 is/are pending in the application.
- Of the above claim(s) 25-28 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15, 19-24 and 29-32 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 29, line 3, where --a-- should be inserted before "genetic".

This application contains claims 25-28 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-15, 19-24, 29 and new claims 30-32 are under examination.

Applicant's amendments of 26 August 2002 and accompanying arguments have overcome the claim objections, the rejection under 35 USC 101, the rejections under 35 USC 102 over each of Visser et al and Safford et al, and the rejections under 35 USC 112, second paragraph, except as noted below.

Claims 2-3 and 8-11 remain, and new claims 30-32 are, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated for claims 2-3, 8-11 and 16-18 on the bottom of page 3 of the last office action.

Claim 30 is indefinite in its recitation of "process...plant cells comprising introducing" as it is unclear whether the process of line 1 or the plant cells of line 6 comprise the subsequently recited claim elements. If the process were intended, then insertion of a comma after "cells" in line 6 would obviate this rejection.

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Claims 1-15, 19-24 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action on pages 4-6 for claims 1-24 and 29. mt

Claims 1-15, 19-24 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to nucleic acid constructs comprising at least 1330 base pairs of the potato GBSSI gene and the entire coding sequence of the potato BEI gene, each in antisense orientation with respect to its own promoter, does not reasonably provide enablement for claims broadly drawn to plant transformation with a single gene which somehow reduces the expression or activity of both GBSSI and BE, a single gene which encodes a single protein with the enzymatic activity of both GBSSI and BE, nucleic acid molecules from non-potato sources, nucleic acid molecules encoding other types of BE besides BEI, nucleic acid molecules encoding a multitude of ribozymes thereto or comprising a multitude of in-vivo-produced mutants thereof, or nucleic acid molecules comprising a multitude of fragments thereof encoding a multitude of fragments of the protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 6-10 of the last office action for claims 1-24 and 29. mt

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Claims 1, 3, 5-6, 12-15, 19, 21-24 and 29 remain rejected under 35 U.S.C. 102(b) as being anticipated by Flipse et al, as stated on pages 11-12 of the last office action for claims 1-6, 8, 10, 12-16, 19-24 and 29.

Claims 1-15, 19-24 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ek et al (U.S. 6,169,226 filed 29 May 1998) taken with Visser et al and Safford et al, in view of Kossman et al, as stated on pages 12-14 of the last office action for claims 1-24 and 29.

No claim is allowed.

Applicant's arguments filed 26 August 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the indefiniteness rejections have all been overcome in view of the amendments of 26 August 2002, and in view of the disclosure of double constructs in the specification. The Examiner maintains that the claims are not limited to a single nucleic acid comprising a double construct, but are instead broadly drawn to a single nucleic acid which somehow encodes a protein with two different enzyme activities or which somehow encodes another nucleic acid which inhibits two different enzyme activities.

Applicant urges that the written description rejection is improper, given the asserted ability of the skilled artisan to utilize homology comparisons to identify other genes, and given the description in the specification of other GBSSI and BE genes or enzymes. The Examiner maintains that the excerpted portions of the specification disclose the existence and isolation of other GBSSI genes, but do not disclose the structural features conserved by these genes, nor do

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they disclose or describe any fragments thereof. In addition, no description of any BEI genes is provided. Finally, it is noted that most of the claims are not limited to GBSSI or BEI genes, but are instead broadly drawn to any genetic modification or the introduction of any nucleic acid molecule which somehow reduces the activity of the enzymes encoded by these genes.

Applicant's mere assertions regarding homology are not probative.

Applicant urges that the scope of enablement rejection is improper, given the assertions that various non-exemplified techniques for gene inhibition were known, and the knowledge that full-length genes were not required for antisense inhibition. The Examiner maintains that such assertions are not sufficient to rebut the evidence of unpredictability provided by the cited publications and scientific reasoning of the Examiner. Additionally, the instant specification is silent with regard to the evaluation of a multitude of non-exemplified fragments, genes, or techniques. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Applicant urges that the art rejection over Flipse et al is improper, since that reference taught chemical mutagenesis of the GBSSI gene rather than transformation as instantly claimed. The Examiner maintains that claim 1 does not recite any transformation, and that the remaining claims merely recite transformed plants which contain "at least one" foreign nucleic acid, wherein said plants exhibit reduced activity of GBSSI and BEI. The transformed plants taught by Flipse et

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al meet these criteria. Note that the Examiner has removed claims 2 and 4 from this rejection, since claim 2 specifies that the reduction of both the GBSSI and BEI enzyme activities are each due to the introduced nucleic acid.

Applicant urges that the obviousness rejection is improper, given the failure of the prior art to teach or suggest the unexpected results of plants producing starch with increased phosphate content and decreased gelatinization temperature. The Examiner maintains that such unexpected results were only obtained by plant transformation with nucleic acid constructs comprising at least 1330 base pairs of the potato GBSSI gene and the entire coding sequence of the potato BEI gene, each in antisense orientation with respect to its own promoter. However, the claims are not so limited. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 12, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", followed by a large stylized "V" or "U" mark.